AUG 1 7 2000

K002086

510(k) Summary

Trade Name: **PrimaFlow**

Sponsor: DMG USA, Inc.
414 South State Street
Dover, DE 19901
Registration # not yet assigned
Owner/Operator No. 9005969

Device Generic Name: Dental restorative material

Classification: According to Section 513 of the Federal Food, Drug, and Cosmetic Act, the device classification is Class II.

Predicate Devices:
The proposed DMG-USA PrimaFlow restorative material is substantially equivalent to several currently marketed dental restorative compomer materials:

Product Name	510(k) #	Manufacturer
Compomer LC	K987697	SternOmega
Dyract	K945364	Dentsply Int'l.
Dyract AP	K973235	Dentsply Int'l.
Compoglass	K974577	Ivoclar North America
Hytac	K992909	ESPE
Ionosit Microspand	K935689	Foremost Dental

Product Description/Indications for Use:
PrimaFlow is a single-paste, light-curing, radiopaque dental filling material indicated for use in minimally invasive restorations, Class III and V restorations, bases, extended fissure sealing and restorations of all classes of cavities in deciduous teeth. The material is offered in prefilled syringes and microtips.

Safety and Performance:
This submission is an Abbreviated 510(k) as described in FDA's guidance document entitled "The New 510(k) Paradigm - Alternate Approaches to Demonstrating Substantial Equivalence in Premarket Notifications." In support of this 510(k), DMG-USA has provided information to demonstrate conformity with FDA's guidance document entitled ***Guidance for Industry and FDA Staff: Dental Composites - Premarket Notification*** (November 1998).

Conclusion:
Based on the indications for use, technological characteristics, and comparison to the predicate device, the PrimaFlow restorative material has been shown to be safe and effective for its intended use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 17 2000

DMG USA, Incorporated
C/O Ms. Pamela Papineau
Delphi Medical Device Consulting
5 Whitcomb Avenue
Ayer, Massachusetts 01432

Re: K002086
Trade Name: PrimaFlow
Regulatory Class: II
Product Code: EBF
Dated: June 16, 2000
Received: July 10, 2000

Dear Ms. Papineau:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4692. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,

Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K002086

510(k) Number (if known): K002086

Device Name: PrimaFlow

Indications for Use:

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(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-the -Counter Use ____
(Per 21 CFR 801.109)

Susan Runner
(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices
510(k) Number K002086